

AFFIDAVIT OF HERBERT L. DuPONT, M.D.

BEFORE ME, the undersigned authority, on this day personally appeared Herbert L. DuPont, M.D., who, after being duly sworn by me, stated under oath, as follows:

1. My name is Herbert L. DuPont. I am over the age of 21, and I am competent to testify to the facts stated herein. This affidavit is based on my personal knowledge and training.

2. A copy of my Curriculum Vitae is attached.

3. I have reviewed material provided by the state of Oklahoma and the consultants to the state giving opinions as to the merits of their case.

4. I am confining my opinions as offered herein to those I can express to a reasonable degree of medical- and when appropriate a reasonable epidemiologic-certainty.

5. My Background and Capabilities

To indicate the appropriateness of my reviewing the above records and providing my comments, I have worked for approximately thirty years performing research in the field of enteric (intestinal) infections and infectious diseases in the U.S. and abroad. I have served as an infectious disease epidemiologist (person who studies epidemics of infectious diseases in human populations) with the U.S. Centers for Disease Control and

Prevention (CDC). After leaving the CDC, I was asked to serve for a five-year term the CDC's Board of Scientific Counselors, who advised the agency on policy and programs. I have been consulted and had research grants funded by the U.S. Environmental Protection Agency dealing with water quality and infectivity for humans of water microbes and have served as an Advisor to the U.S. Food and Drug Administration. I have served as president of the two U.S. national organizations dealing with infectious diseases, the Infectious Diseases Society of America and the National Foundation for Infectious Diseases and have directed academic programs in medical schools and public health institutions in the U.S. I have authored or co-authored more than 570 scientific papers and 19 textbooks, most of which have been in the field of infectious and intestinal infectious diseases. I direct research programs dealing with diarrhea in the United States and abroad, currently working on three continents. I am considered an international expert in infectious diseases, diarrhea and intestinal infection. I have been listed in the Best Doctors in America and America's Top Doctors for infectious disease each year of the two publications (1992-2007 and 2001-2007, respectively). March 21, 2007 I received the Maxwell Finland Award for Scientific Achievement from the National Foundation for Infectious Diseases in Washington, DC. This is the top national award in

infectious diseases. Of relevance to this case, I am currently Director of the Center for Infectious Diseases and Professor of Epidemiology at the University of Texas – Houston School of Public Health and have taught the principles of the diagnosis and evaluation of intestinal infections, diarrheal illness and water-borne and food-borne disease outbreaks to public health and medical students for the past thirty years. Also, I am Chief of Internal Medicine at St. Luke's Episcopal Hospital, a 700-bed university hospital responsible for training doctors in internal medicine including infectious diseases, nephrology, hematology, gastroenterology, as well as eight other medical specialties.

6. Sources of Enteric (Intestinal) Infectious Diseases in the U.S.

- a. Intestinal infections can result from ingestion of food (foodborne disease), water (waterborne disease) or other beverages, from one infected person to another (person-to-person spread) or from the environment including from animals or inert surfaces recently contaminated by an infected person or animal source.
- b. In considering the source of an intestinal infection it is useful to consider the potential level of contamination of the source to help put the problem into perspective. Food has

great potential to be contaminated by human handlers and preparers (see later discussion of the harboring of microbes by humans) who leave food out at room temperature before or after cooking. Food serves as a growth medium for bacteria providing nutrients and moisture where the number of organisms can reach dangerous levels as the food remains at room temperatures or even lower temperature levels for important periods of time. This is the reason that food is the major source of intestinal infections in the United States causing an estimated 76 million cases of illness each year leading to hospitalization in 325,000 persons and resulting in 5,000 deaths. The EPA has estimated that drinking water causes approximately 8.5% of the acute gastroenteritis cases in those served by community water services. Rates of illness from ground water (source of drinking water for ~40-45% of U.S. population) are influenced by adequate treatment of the water source by the well-owner. The number of disease outbreaks from water not intended for drinking including recreational water appears to be lower as determined by passive surveillance. Certainly the potential

risk from enteric infectious diseases is greater when consuming contaminated water versus incidental swallowing while recreating or swimming in contaminated water.

- c. In contrast to the frequent occurrence of human illness outbreaks from heavily contaminated food, the minimal level of contamination of water is associated with a low frequency of illness outbreaks in humans in the United States. In the developing world where there occurs a high level of fecal contamination of the water systems from human excreta, waterborne disease is more important. In the United States we are fortunate to have excellent water systems and ground water.
- d. To better understand the relationship of the level of contamination and the expected microbe causing illness in exposed persons it would be useful to introduce the concept of inoculum or dose of microbes needed to produce human illness. All infectious agents show a predictable dose-illness response for humans. The intestinal microbes that cause human disease can be classified into “low-dose”, where as few as 10 organisms can produce disease,

“moderate-dose” where 1,000 bacteria or more (often >100,000) are needed to produce disease and “high-dose” where millions of organisms are required to have persons become ill. Most of the data on dose-response for intestinal pathogens have been derived from human feeding experiments where various challenged doses were administered to healthy adult humans. I have participated in or directed many of the feeding studies establishing the dose-response standards.

- e. The low-dose intestinal microbes important in human illness include *Shigella*, *Giardia*, *Cryptosporidium*, Shiga toxin-producing *E. coli* such as *E. coli* O157:H7, and noroviruses. The intermediate-dose pathogens consist of *Campylobacter*, *Salmonella* and invasive *E. coli*. The high-dose microbes include enterotoxigenic *E. coli* (ETEC), enteroaggregative *E. coli* (EAEC) and *Vibrio cholera*, the cause of cholera. ETEC is the most important cause of diarrhea when persons visit a developing region, and the organism is causing an increased number of foodborne infections in the U.S. as foreign foods are being imported to our country. EAEC is

also a foodborne pathogen and causes travelers' diarrhea and infantile diarrhea in developing regions. The moderate-dose and all of the high-dose pathogens are spread by contaminated food since high growth requirements are needed for the organism to reach sufficient levels for human infection. Illness in humans with the low contamination levels seen with recreational and ground water is seen only for the low-dose pathogens. Also, spread of an intestinal microbe from one person to another person is seen only for the low-dose pathogens where the small number of microbes can be shared between people in direct contact.

7. Steps in Investigating an Outbreak of Intestinal and/or

Waterborne Infections

- a. An outbreak of illness is defined as having more cases of an illness occurring over a unit of time than normally occurs. Such outbreaks can only be detected through formal outbreak investigations well known by public health officials. Whenever there is a suspicion that a waterborne or foodborne outbreak has occurred, the required investigation is performed in well established steps developed by the CDC

and provided to health departments around the country. The steps to be followed in investigating a waterborne or foodborne outbreak are provided in a CDC website (<http://www.cdc.gov/excite/classroom/outbreak/steps.htm>).

- b. Without going through the methodical steps of an investigation for disease rates and illness causation it is impossible to confirm the presence of a health risk or to implicate a common source (drinking water, recreational water or food) in a community setting.
- c. In my opinion, to categorically state that because water contains markers of fecal contamination it is causing important human illness is a non-scientific and non-epidemiological conclusion that is hard to justify. An epidemiologic evaluation was not felt to be necessary in the Illinois River watershed (IRW) due to lack of evidence of a health problem. If there had been evidence of increased enteric disease in the area, a formal outbreak investigation would have been indicated. The reason for an outbreak investigation would be:

- 1) To determine if an outbreak of human illness has

occurred;

- 2) To establish the occurrence of clustering of cases following a common exposure;
- 3) To determine an incubation period of disease (time from exposure until illness develops) and to construct a formal epidemic curve, both critical in establishing the cause of illness;
- 4) To identify risk factors for the occurrence of illness among those exposed and acquiring or not acquiring the illness (e.g. consumption of ground water or for waterborne disease swimming versus boating, submerging the head below the surface, ingesting water, etc.); and finally,
- 5) To implement an intervention program preventing continual exposure and disease occurrence.

d. I reviewed no information provided by the state of Oklahoma to show that rates of enteric disease of potential poultry origin (Salmonella and Campylobacter) showed a medically or epidemiologically meaningful increase over the years that

state poultry activities were increasing. Furthermore, I know of no time that the health authorities in Oklahoma issued a health advisory warning for persons drinking or swimming in the Illinois River water system. Moreover, there was no outbreak investigation in the IRW performed by the Oklahoma health authorities.

8. Lack of Evidence of a Health Threat From Oklahoma Department of Health

According to his deposition testimony, Dr. Michael Crutcher, the Commissioner of the Department of Health (DOH) for the state of Oklahoma indicated that in the past 12 years there have been no disease outbreaks, nor disease clusters of concern to the DOH in the IRW. Furthermore Dr. Crutcher indicated that the DOH has not observed a statistically (significant) elevated rate of intestinal infections in the IRW including those due to Salmonella and Campylobacter. Based on the observations of the Oklahoma DOH, they elected not to conduct a formal disease outbreak investigation designed to identify human health problems from enteric microbes among persons living in the IRW. Based on the information I have reviewed, I agree with Dr. Crutcher's conclusions.